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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	36

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

Application No.	Applicant(s)
08/726,093	Fuchs et al.
Examiner	**Art Unit**
Ardin Marschel	1631

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Mar 19, 2001*

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *54, 57-62, 64-71, and 75-118* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *54, 57-62, 64-71, and 75-118* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirem

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [X] Notice of References Cited (PTO-892)

16) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) [X] Interview Summary (PTO-413) Paper No(s). *31*

19) [ ] Notice of Informal Patent Application (PTO-152)

20) [ ] Other:

The request, filed 3/19/01, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/726,093 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' arguments, filed 3/19/01, have been fully considered but they are not persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration of the instant application, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

The numbering of claims is not accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 CFR 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 72-113, 113(second occurrence), and 114 been renumbered as claims 75-118, respectively. It is noted that claims 72-74 were previously pending and canceled.

Claims 54, 57-62, 64-71, and 75-118 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention.

In claim 54 an apparatus is claimed with a PNA probe associated with a particle but without clarifying the cooperativity between said probe and the apparatus zones. Is the probe in the apparatus or a separate reagent which is not connected to the apparatus? Clarification via clearer claim wording is requested. Claims which are directly or indirectly dependent from this claim are also vague and indefinite due to said dependence.

Claims 57 and 115 are vague and indefinite as to how a sample incubation zone can be in communication with both a introduction and separation zone where the introduction and separation zones are in communication in part b). Is the incubation zone inbetween the introduction and separation zone? If so, it is unclear how the separation zone is in communication with the introduction zone in part b) without this being through the incubation zone. Clarification via clearer claim wording is requested. Claims which are directly or indirectly dependent from this claim are also vague and indefinite due to said dependence.

Similarly, claim 58 is vague and indefinite as to how it can be in communication with the introduction and separation zones without a PNA probe mixing zone inbetween in order to practice part b). Is another zone implied for PNA mixing? An implied

zone is not clearly and concisely cited. It is noted that clear and concise wording to describe the invention is required under 35 U.S.C. § 112, second paragraph, and that implications are deemed not clear and concise. Clarification via clearer claim wording is requested. Claims which are directly or indirectly dependent from this claim are also vague and indefinite due to said dependence.

Similarly, claim 71 cites a sample introduction zone without defining its cooperativity in the apparatus. Also a PNA disposition is given in part b) without a corresponding zone definition and is thus vague and indefinite. Clarification via clearer claim wording is requested. Claims which are directly or indirectly dependent from this claim are also vague and indefinite due to said dependence.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 54 and 57, 86, 89, 92-94, 97, 107-110, 115, and 116 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Weininger et al.(P/N 5,871,902).

PNA (probe nucleic acid) probes with a bound bead and detectable label is disclosed in column 10, line 37, through column 11, line 3, as being probe nucleic acids with a bead solid support and, optionally, with detectable label attached. In column 27, lines 15-42, a machine embodiment is disclosed which is deemed to be an apparatus as instantly claimed. The PNA-particle material is bound via its TBA(target binding assembly) to sample nucleic acid in one sample introduction reaction solution and then transferred to glass fiber matrix which therefore is in communication during said transfer. The matrix is a separation zone in that it separates hybrids from unbound material. It is also noted that sample is pipetted into a reaction cell, a sample introduction zone where the pipette contains sample for introduction into said cell, which is reasonably interpreted as a incubation zone as in instant claim 57. Again as noted above the incubation zone, reaction solution, is communicated to the separation glass fiber zone thus also anticipating instant claim 57. Low ionic buffer is utilized in PNA/target hybridization as given in column 36, lines 39-47, as also required in instant claim 89. It is acknowledged that the instant application exemplifies PNA as a peptide nucleic acid but that no succinct definition has been found in the instant specification to prevent a PNA of the above cited reference from being considered to anticipate the instant claims. It is suggested that the instant claims be amended to replace PNA with

the phrase "peptide nucleic acid" which would overcome this rejection.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 54, 57-59, 61, 64-71, 75-86, 88-94, and 96-118 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilding et al.(P/N 5,726,026); taken in view of Summerton et al.(P/N 5,217,866).

Wilding et al. discloses an apparatus with mesoscale or capillary channel therein for performing various biochemical analyte assay methods. The mesoscale or capillary sizes are described in column 7, line 57, through column 8, line 7. PCR amplification may be performed prior to detection of the desired product nucleic acid as noted in the abstract. In the section

entitled "SUMMARY OF THE INVENTION" in columns 3-5, the mesoscale preparation of sample, assay incubations, reactions such as PCR, and hybridization detection are summarized as being performed on mesoscale apparati. Sample sieving in the channel is described in column 16, lines 14-46. The practice of a plurality of sample detection analyses done simultaneously is described for such a device in column 4, lines 17-23. In column 4, lines 36-41, the detection is suggested and motivated as being performed with a binding substance which may be immobilized either on a stationary or mobile support. Such supports include particles as noted in column 10, lines 59-65. The usage of PNA-particles as such a binding reagent on a support is not described in the reference but, as noted above, the detection of nucleic acid with binding substances via hybridization is suggested.

Summerton et al., taken as a whole describes the practice of nucleic acid detection via PNA hybridization. In particular PNA-particle or bead reagents are described as being usable for such assays and prepared as noted in column 17, line 65, through column 18, line 56. Such PNA-support reagent is utilized in hybridization detection in examples in column 50, line 5, through column 51, line 15.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the device of Wilding et al. with a binding reagent/particle assay as described in Summerton et al. because Wilding et al. given generic suggestion for the use of such reagents as would be

available as described by Summerton et al. thus resulting in the practice of the instant invention.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)305-3014 or (703)308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524.

June 1, 2001

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER